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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/055,818 04/06/98 GUTIERREZ-ROCCA J I-132D

000530 HM12/0507
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EXAMINER

RAYMOND, R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624
DATE MAILED:

18
05/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/055,818

Applicant(s)

Gutierrez-Rocca et al.

Examiner

Richard L. Raymond

Art Unit

1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 19, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-118 is/are pending in the application.
- 4a) Of the above, claim(s) 53-117 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 13-41, and 118 is/are allowed.
- 6) ☒ Claim(s) 42-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 and 8 20) ☐ Other: _____

#7 in the last action should have been #13

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DETAILED ACTION

Response to Amendment

1. In view of the amendment of March 19, 2001, the Section 112 and art rejections of record have been overcome. Claims 53-117 remain withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-11 and 13-41 and new claim 118 are herein allowed. Claims 42-52 are newly rejected below.

Claim Rejections - 35 USC § 112

2. Claims 42-52 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions of taxanes and vehicles comprising about 5-70% by weight of a co-solubilizer, does not reasonably provide enablement compositions containing any and all vehicles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Note that an unpredictable and unexpected use, absorption of taxanes, is involved. Representative exemplification for the scope of the present vehicles is not seen present.

Conclusion

3. This action is not made final in view of applicants' attempt to overcome all the issues.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Raymond whose telephone number is (703) 308-4523. The examiner can normally be reached on weekdays from 9:30 AM to 6:00 PM.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

rr

May 4, 2001


Richard L. Raymond
Primary Examiner
Art Unit 1624